

Applicant: Rümpler et al.
Application No.: 10/560,372

REMARKS/ARGUMENTS

After the foregoing Amendment, Claims 3 – 14; 16 – 29 and 33 – 36 are currently pending in this application. Claims 1– 2, 30–32 and 37 were previously cancelled. Claim 15 is presently cancelled. Claim 36 is amended. Applicants submit that no new matter has been introduced

Claim Rejections - 35 USC §103

Claims 3, 5 – 6, 8 – 9, 11 – 14, 15 – 26, 28 – 29, and 33 – 36 were rejected under 35 U.S.C. §103(a) as obvious over WO 01/83727 to Barendse et al. in view of U.S. Patent No. 4,354,450 to Nagahama et al and further in view of U.S. Patent No. 3,777,874 to Birckhead and U.S. Patent Application Publication No. 2006/0105024 to Andela.

Claim 4 was rejected under 35 U.S.C. § 103(a) as obvious over Barendse in view of Nagahama, in view of Birckhead, in view of Andela and further in view of U.S. Patent No. 4,233,007 to Karlsson.

Claims 7 and 10 were rejected under 35 U.S.C. § 103(a) as obvious over Barendse in view of Nagahama, in view of Birckhead, in view of Andela and further in view of U.S. Patent No. 4,100,262 to Miller.

Applicants respectfully traverse the rejections.

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Independent claim 36 has been amended to recite “with both types of nozzles being present in an injection zone (22) in the core zone above the deflecting part”, which is supported by paragraph [0033], line 18, and paragraph [0026], lines 5-9 of the published application (US 2007/0093403). Further, independent claim 36 has also been amended to recite “the average value of the residence time of the enzymes in the processing chamber amounts to less than 1.5 hours” originally found in claim 15.

In the Action, the Examiner states that previously amended claim 36 did not include any limitation directed to the residence time. The present amendment of claim independent claim 36, addresses this by specifically setting forth at the residence time of the enzymes in the processing chamber amounts to less than 1.5 hours.

Further, the Examiner states that Andela teaches that an enzyme is spray dried and the introduction of an inert compound by co-drying, however, admits that the use of nozzles is not specifically mentioned. He states that the process of co-drying implies for one of ordinary skill in the art that additional material is introduced separately. However, this is a narrow interpretation. Firstly, co-drying may also include the drying of a simple mixture of first and second materials. Secondly, the process of spray-drying, disclosed in Andela is different from that

used in the presently claimed invention.

The Examiner fails to consider the following differences. Firstly, only spray drying or multistage drying is mentioned in Andela for enzyme coating of granulates. The materials used as inert materials i.e. inorganic salt, maltodextrines, granulated flour (see paragraph [0042]) are powders and are added prior to or during the granulation. Secondly, there is no mention of nozzles as claimed in Andela, especially no three- or four-way nozzles, which offer the advantage of allowing particularly fine atomization, and especially no separate nozzles for the additives, as claimed. Thirdly, the co-drying disclosed in Andela is interpreted with hindsight as applicable to the presently claimed invention. Fourthly, no process comparable to the very specifically claimed process with the specifically claimed equipment is suggested at all.

The Examiner relies on Hartman as disclosing a “plurality of heads” for nozzles. Independent claim 36 recites, *inter alia*, “atomizing the at least one inert material via at least one inert material atomizing three way nozzle or four way nozzle that is separate from at least one liquid enzyme atomizing nozzle for atomizing the liquid enzyme formulation during the drying and granulation process”.

There are distinct differences between the “plurality of heads” and the

nozzles as claimed. Firstly, the type of nozzles is different from the three way or four way nozzles claimed in the present invention. Hartman describes at column 4, lines 31 - 40:

Advantageously, the nozzle 36 is not as vulnerable to being plugged by the air being directed to the fluidized-bed because the openings in the respective heads 38 are much larger than the holes in the prior art constructions. In addition, there are many less nozzle assemblies 30 required than pipes of the prior art design. This requirement for less nozzle assemblies 30 than the prior art pipes follows because of (a) the size of the openings in the heads 38 and (b) the angular orientation of the heads 38.

Given that the claim is directed to “at least one inert material atomizing three way nozzle or four way nozzle” the structure provided by Hartman fails to show the claimed nozzle.

Even assuming *arguendo* that the two or four heads 38 in Hartman could possibly be interpreted to fall under this wording, several differences still exist. Namely, the device of Hartman is a fluidized bed directed to a combustion process in a steam combustion system (see column 1, line 2). One of ordinary skill in the art in the field of enzymes would, rightfully, never consider such a crude device for a process of making enzyme preparations. Furthermore, Hartman fails to show or

suggest two different types of nozzles for feeding in enzymes as claimed. It is also noted that in the device of Hartman, the deflection piece is not present and no circular flow exists.

The Examiner appears to have added specifics not disclosed or suggested in Andela and then used the prior art he thus modified to selectively show features of the present invention, picking certain features from the present invention and interpreting them as being shown by Andela

It is further noted that the spray drying (or multistage drying) mentioned in Andela would lead to a quite inhomogeneous particle size and therefore requires a coating in order to achieve useful pellets at all. Thus, it is possible and can be tolerated in the set-up of the process in Andela that the granules, which are only intermediates, not the final product which always requires a coating, can have properties which cannot be tolerated for a final product as in the present invention.

Further, a continuous process as it is possible by the present invention would not appear possible by Andela since Andela describes batch processes.

In contrast, the homogeneous final results provided by the present invention, with the directed gas stream and the adjacent spraying nozzles for adding enzyme solution and inert material, allow for the manufacture of very homogeneous particles, with regards to both size and internal homogeneity, even where the

solutions of inert material and enzyme are not compatible.

Finally, in Andela there is no example whatsoever given that would correspond to the granule formation by spray drying or multistage drying –rather a process using a pelleting press (see Examples “General Methods”) is used where the food granules and the premix of choice are mixed and then pelleted. Thus, there is no separate admixing or nozzle used, and the process is a batch process and does not allow for at least facultative continuous manufacture.

Regarding Barendse, which the Examiner confirms that teaches a fluid bed apparatus but lacks a circular flow. In addition, as is not mentioned by the Examiner, Barendse also lacks the separate addition of inert material (only additives to the enzyme solution or slurry are mentioned, see page 4, 2nd paragraph). It also lacks the deflection part.

The Examiner relies on Nagahama to show a circular flow and states that Fig. 6 shows a circular flow arranged in an axial direction of the reaction chamber. Independent claim 36 recites: “forming a circular flow of solid matter, through material return into the gas stream, arranged in an axial direction of the reaction chamber”. While it might be considered that the vertical axis in the middle of the device is an axis and the flow surrounding it is circular, it is at least clear that Nagahama, besides not mentioning enzymes, does not mention any further

materials. It expressly states that “the same chemical substance as that of the seed particles” or a for covering seed particles containing at least a chemical substance different from that of the seed particles (column 9,lines 22 to 32). That is, only one substance (or its solution) is sprayed at a time. Thus, no different nozzles are shown or required. In the presently claimed invention, first different nozzles are present and second the inert material nozzles are three or four way nozzles. Seed materials are always required, which are not required in the present invention. Only urea is mentioned in the example, no enzymes. Thus, apart from the different chemical, also the combination with an inert material in the same material matrix is missing (see feature g of present claim 36), the two different types of nozzles are missing, and still the deflection piece is absent.

In a next step, ignoring the additional aforementioned features, besides the circular flow, the Examiner then quotes Birckhead in support of the deflection piece. However, in the present case the deflection piece (or part) is directing the stream of the gas jets/processing stream (without material) upwards, while in the case of Birckhead (See Fig. 6) the particles enter via nozzle 206 and then are redirected by the fan 68. Thus, the function is different, and the location of the nozzle as well (see also column 16, lines 24 to end, especially lines 39 and 52 to 54. Therefore, there is a structurally different location and way of use.

In addition, this document relates to the quite remarkably remote technical area of coating of pre-formed particulate thermoplastic material (see column 1, first paragraph), and the powder deposition station 12 (see Fig. 1) is quite a remote device. In the present case, no such material is present. Enzymes are not mentioned or suggested at all. Further, one of ordinary skill in the art would **never** consider a device for coating with particulate thermoplastic material with regard to enzymes. Further, no addition of the second material to form an addition to the matrix or parts therefrom from an enzyme is given. No circular flow exists.

Thus not only the material is different, but all the rest, including again the lack of different types of nozzles and the (essentially simultaneous) spraying of inert material and enzyme formulation. Birckhead even fails to suggest the present deflection piece or part.

Therefore, all of the references cited are akin to mosaic pieces with generalizations and use of very remote technology areas with the aim to cobble together the features of the presently claimed invention. However, given the differences and the missing features set forth above, a *prima facie* case of obviousness cannot be made.

Further, the Examiner fails to explain why one of ordinary skill in the art would and how he could in any way be motivated to use the sequence of selection of

features and the resulting sequence of document quotations to arrive at the present invention – only by using hindsight reconstruction, a puzzle or mosaic is created from various documents, without any hint why such combination would be considered by a person skilled in the art, to achieve the present invention.

The M.P.E.P. at 2142 cautions against such impermissible hindsight reasoning:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Therefore, the examiner has also failed to provide a prima facie case of

obviousness due to impermissible hindsight.

Further, the examiner has not adhered to the USPTO 2007 KSR Examiner Guidelines, which states that every obviousness rejection requires:

- appropriate findings of fact;
- a reasoned explanation; and
- a legal conclusion of obviousness.

It is noted that under the guidelines, even though the components are known, the combining step is theoretically possible, and the result is predictable, the claimed invention is nonobvious when the combining step involves such additional effort that no one of ordinary skill would have undertaken it without a recognized reason to do so.

Moreover, the March 2009 Guidelines for Determining Obviousness in View of the Supreme Court Decision in KSR set forth:

When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. . . . There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *KSR* at 1396.

In formulating a rejection under 35 U.S.C. § 103, the

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examiner should focus on the state of the art and not impermissible hindsight, e.g. applicant's disclosure.

See *KSR* at 1397 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.") (citing *Graham*, 383 U.S. at 36).

The examiner has failed to meet the threshold set forth by these guidelines.

Claims 3, 5 – 6, 8 – 9, 11 – 14, 16 – 26, 28 – 29 and 33 – 35 depend either directly or indirectly from claim 36, which applicants believe to be allowable for the same reasons above. Accordingly, withdrawal of the § 103 rejection of claims 3 – 29 and 33 – 36 is respectfully requested.

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Conclusion

If the Examiner believes that any additional minor formal matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to materially advance the prosecution of this application, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application, including claims 3 – 14; 16 – 29 and 33 – 36, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

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